

1 Vanessa R. Waldref
2 United States Attorney
3 Brian M. Donovan
4 John T. Drake
5 Assistant United States Attorneys
6 Post Office Box 1494
7 Spokane, WA 99210-1494
8 Telephone: (509) 353-2767
9

10 UNITED STATES DISTRICT COURT
11 EASTERN DISTRICT OF WASHINGTON
12

13 JEREMY OLSEN,

14 Plaintiff,

15 vs.

16 XAVIER BECERRA, in his official
17 capacity as Secretary of the United States
18 Department of Health and Human
19 Services,
20

21 Defendant.

No. 2:21-cv-00326-SMJ

DEFENDANT'S ANSWER TO
COMPLAINT

22 The Defendant, Xavier Becerra, Secretary of Health and Human Services
23 ("Defendant"), through counsel, respectfully answers Plaintiff's Complaint, ECF No.
24 1, as follows.
25

26 **PREFATORY STATEMENT**

27 "It is often better to acknowledge an obvious mistake than defend it." *Gate*
28 *Guard Servs., L.P. v. Perez*, 792 F.3d 554, 555 (5th Cir. 2015). Defendant
acknowledges that it made an obvious, unfortunate error in denying the Medicare claims
at issue in this case. Defendant has identified the root cause of the error, and taken

1 affirmative steps to ensure that Plaintiff will not be inconvenienced again.

2 Defendant also recently completed notice and comment rulemaking that
3 culminated in the publication of a final rule that classifies continuous glucose monitor
4 (CGM) devices like those used by Plaintiff as “durable medical equipment” under
5 Medicare Part B. *See* 86 Fed. Reg. 73860, 73896, (Dec. 28, 2021), available [here](#). This
6 new rule, which takes effect on February 28, 2022, effectively ensures that future CGM
7 claims submitted by Plaintiff and other similarly-situated Medicare claimants will be
8 covered.
9

10
11 Consistent with the admissions herein, Plaintiff is entitled to an administrative
12 remand to the Secretary of Health and Human Services for payment of his claims (which
13 payment the Secretary has already issued), and to an award of costs and attorney’s fees
14 under the Equal Access to Justice Act. Judgment should be entered in Plaintiff’s favor
15 to that effect.
16
17

18 I. INTRODUCTION

19 1. This paragraph consists of Plaintiff’s legal conclusions and
20 characterization of this lawsuit, to which no response is required.
21

22 2. Defendant admits that Plaintiff previously filed a lawsuit with respect to
23 claims for continuous glucose monitor (CGM) coverage in the matter of *Olsen v.*
24 *Becerra*, Case No. 20-cv-00374-SMJ (*Olsen I*). The remainder of this paragraph
25 consists of Plaintiff’s legal conclusions and characterization of this lawsuit, to which no
26 response is required.
27
28

1 3. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
2 entry of the Court's decision in *Olsen I*. Defendant denies that he acted in bad faith.
3 Defendant affirmatively avers that he investigated why Plaintiff's claims were
4 erroneously denied, and determined that an employee of the Medicare Administrative
5 Contractor ("MAC") responsible for processing Plaintiff's claims failed to make a
6 manual adjustment to the submission code assigned to Plaintiff's claims in the MAC's
7 claims processing system that was needed to facilitate payment, as the employee had
8 been instructed to do following the decision in *Olsen I*. The MAC and its employees
9 have been re-educated to ensure that the required manual adjustment is made going
10 forward. The remainder of this paragraph consists of Plaintiff's legal conclusions and
11 characterization of this lawsuit, to which no response is required.
12
13
14

15 4. Defendant admits he erroneously rejected Plaintiff's CGM claims after
16 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
17 allegations in this paragraph.
18

19 5. Defendant admits he erroneously rejected Plaintiff's CGM claims after
20 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
21 allegations in this paragraph.
22

23 6. Defendant admits he erroneously rejected Plaintiff's CGM claims after
24 entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of
25 Plaintiff's legal conclusions and characterization of this lawsuit, to which no response
26 is required.
27
28

II. JURISDICTION

7. This paragraph consists of Plaintiff's legal conclusions regarding subject-matter jurisdiction, to which no response is required.

8. This paragraph consists of Plaintiff's legal conclusions regarding subject-matter jurisdiction, to which no response is required.

9. This paragraph consists of Plaintiff's legal conclusions regarding venue, to which no response is required.

III. PARTIES

10. Admitted.

11. Admitted.

IV. FACTUAL BACKGROUND

12. Defendant admits that Plaintiff previously filed a lawsuit with respect to claim for CGM coverage in *Olsen I* which contained Plaintiff's information and allegations regarding diabetes and Plaintiff's characterization of the Medicare appeals process.

A. Durable Medical Equipment

13. This paragraph consists of Plaintiff's legal characterization of Medicare coverage for "durable medical equipment" under 42 U.S.C. § 1395x(n), to which no response is required.

14. This paragraph consists of Plaintiff's legal characterization of Medicare coverage for "durable medical equipment" under 42 U.S.C. § 1395x(n), to which no

1 response is required.

2 15. This paragraph consists of Plaintiff's characterization the Secretary's
3 regulations, to which no response is required. The Court is respectfully referred to the
4 cited regulation.
5

6 16. This paragraph consists of Plaintiff's quotation from CMS Ruling 1682-R,
7 to which no response is required. The Court is respectfully referred to the cited CMS
8 Ruling. See [https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-](https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-Rulings-Items/CMS1682R)
9 [Rulings-Items/CMS1682R](https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/CMS-Rulings-Items/CMS1682R).
10

11 **B. CMS-1682-R**
12

13 17. This paragraph consists of a block quotation of a statutory provision, to
14 which no response is required. The Court is respectfully referred to the cited statutory
15 provision.
16

17 18. This paragraph consists of Plaintiff's characterizations and legal
18 conclusions regarding a statutory provision, to which no response is required. The Court
19 is respectfully referred to the cited statutory provision.
20

21 19. Defendant admits that CMS Ruling 1682-R was issued on January 12,
22 2017. The remainder of this paragraph consists of Plaintiff's characterizations and legal
23 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
24 is respectfully referred to the cited CMS Ruling.
25

26 20. This paragraph consists of Plaintiff's quotation from CMS Ruling 1682-R,
27 to which no response is required. The Court is respectfully referred to the cited CMS
28

1 Ruling.

2 21. This paragraph consists of Plaintiff's characterizations and legal
3 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
4 is respectfully referred to the cited CMS Ruling.
5

6 22. This paragraph consists of Plaintiff's characterizations and legal
7 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
8 is respectfully referred to the cited CMS Ruling.
9

10 23. This paragraph consists of Plaintiff's characterizations and legal
11 conclusions regarding CMS Ruling 1682-R, to which no response is required. The Court
12 is respectfully referred to the cited CMS Ruling.
13

14 24. This paragraph consists of Plaintiff's characterizations and legal
15 conclusions regarding the treatment of continuous glucose monitors under Medicare
16 Part B, to which no response is required.
17

18 25. This paragraph consists of Plaintiff's characterizations and legal
19 conclusions regarding the treatment of continuous glucose monitors under Medicare
20 Part B, to which no response is required.
21

22 26. This paragraph consists of Plaintiff's characterizations and legal
23 conclusions regarding a Medicare contractor local coverage determination (LCD), LCD
24 L33822, to which no response is required. The Court is respectfully referred to the cited
25 local coverage determination.
26

27 27. This paragraph consists of Plaintiff's characterizations and legal
28

1 conclusions regarding a Medicare contractor Policy Article A52464, to which no
2 response is required. The Court is respectfully referred to the cited policy article.

3 28. This paragraph consists of Plaintiff's characterizations and legal
4 conclusions regarding the treatment of continuous glucose monitors under Medicare
5 Part B, to which no response is required.

7 29. This paragraph consists of Plaintiff's characterizations and legal
8 conclusions regarding the treatment of continuous glucose monitors under Medicare
9 Part B, to which no response is required.

11 30. This paragraph consists of Plaintiff's characterizations and legal
12 conclusions regarding the treatment of continuous glucose monitors under Medicare
13 Part B, to which no response is required.

15 31. This paragraph consists of Plaintiff's characterizations and legal
16 conclusions regarding the treatment of continuous glucose monitors under Medicare
17 Part B, to which no response is required.

19 **C. Other Litigation Related to CGMs**

21 32. Denied as to the phrase "in general." Defendant has only denied coverage
22 for non-therapeutic (*i.e.*, "adjunctive") CGMs under the authority of CMS Ruling 1682-
23 R. Therapeutic (*i.e.*, "non-adjunctive") CGMs are classified as "durable medical
24 equipment" under CMS Ruling 1682-R, and have thus been covered.

26 33. Defendant denies the first sentence in this paragraph. The second sentence
27 in this paragraph consists of Plaintiff's characterizations and legal conclusions

1 regarding a Local Coverage Article (LCA), to which no response is required.

2 34. Admitted that several district courts have reviewed Medicare Part B
3 coverage determinations for continuous glucose monitors, including this Court in *Olsen*
4
5 *I.*

6 35. This paragraph consists of plaintiff's characterizations and legal
7 conclusions regarding decisions by Medicare Administrative Law Judges, to which no
8 response is required. The Court is respectfully referred to the cited decisions for
9 accurate and complete statements of their contents.
10

11 36. Admitted that several district courts have reviewed Medicare Part B
12 coverage determinations for continuous glucose monitors, including this Court in *Olsen*
13
14 *I.*

15 37. This paragraph consists of Plaintiff's characterizations and legal
16 conclusions regarding several district court decisions, to which no response is required.
17 The Court is respectfully referred to the cited decisions for an accurate and complete
18 statement of their contents.
19

20 38. This paragraph consists of Plaintiff's characterizations and legal
21 conclusions regarding the district court's decision in *Whitcomb v. Azar*, to which no
22 response is required. The Court is respectfully referred to that decision for an accurate
23 and complete statement of its contents.
24

25 39. This paragraph consists of Plaintiff's characterizations and legal
26 conclusions regarding several district court decisions, to which no response is required.
27
28

1 The Court is respectfully referred the cited decisions for an accurate and complete
2 statement of their contents.

3 40. This paragraph consists of Plaintiff's characterizations and legal
4 conclusions regarding a decision of the Departmental Appeals Board, to which no
5 response is required. The Court is respectfully referred to the cited decision for an
6 accurate and complete statement of its contents.
7

8
9 **D. Facts Specific to Mr. Olsen**

10 41. Admitted.

11 42. Admitted.

12 43. Admitted.

13 44. Admitted.

14 45. Admitted.

15 46. Admitted.

16 47. Admitted.

17 48. Admitted.

18 49. Admitted.

19
20
21
22 **E. Prior Litigation Before This Court**

23 50. Admitted.

24 51. Admitted.

25 52. Admitted.

26 53. Admitted.
27
28

1 54. Admitted.

2 55. Defendant admits this Court granted judgment in Plaintiff's favor in *Olsen*
3 *I* (ECF No. 39). The Court is respectfully referred to its prior decision for an accurate
4 and complete statement of its contents.
5

6 56. This paragraph consists of Plaintiff's characterizations of the Court's
7 ruling in *Olsen I*, to which no response is required. The Court is respectfully referred to
8 its prior decision for an accurate and complete statement of its contents.
9

10 57. Admitted.

11 58. This paragraph consists of Plaintiff's characterizations of the Court's
12 attorney fee ruling in *Olsen I* (ECF No. 50), to which no response is required. The Court
13 is respectfully referred to its prior decision for an accurate and complete statement of
14 its contents.
15
16

17 59. This paragraph consists of Plaintiff's characterizations of the Court's
18 attorney fee ruling in *Olsen I* (ECF No. 50), to which no response is required. The Court
19 is respectfully referred to its prior decision for an accurate and complete statement of
20 its contents.
21

22 60. Admitted.

23 **V. The Claims at Issue in this Case**
24

25 61. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
26 entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the
27 allegations in this paragraph.
28

62. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the allegations in this paragraph.

**A. April 19 – July 18, 2019 Claim –
ALJ Appeal No. 3-8946502107/M-20-1269**

63. Admitted.

64. Defendant admits Plaintiff's April 19 – July 18, 2019 Claim was denied by an ALJ decision dated January 31, 2020, prior to this Court's decision in *Olsen I*. Defendant denies the remainder of the allegations in this paragraph.

65. Admitted.

66. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the allegations in this paragraph.

B. March 10, 2021 Claim – ALJ Appeal No. 3-10205345873

67. Admitted.

68. Admitted.

69. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the allegations in this paragraph.

70. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the

allegations in this paragraph.

71. Admitted.

72. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. Defendant denies the remainder of the allegations in this paragraph.

73. Defendant lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and therefore denies the same.

74. Admitted that Plaintiff sought expedited access to judicial review.

75. Admitted.

76. Defendant admits that a Medicare Summary Notice was issued to Plaintiff on or about October 1, 2021. Upon information and belief, fourteen (14) CGM claims from Plaintiff have been paid as indicated in the below chart, including thirteen (13) prior to October 1, 2021 and one (1) after October 1, 2021. The remainder of this paragraph consists of Plaintiff's characterizations of the MSN, to which no response is required.

CCN	Date of Service	Paid Date	Amount Paid
18137823767001	03/15/2018	07/22/2021	\$1,300.66
18172844803001	06/05/2018	07/15/2021	\$1,300.66
18283843973001	09/27/2018	07/15/2021	\$1,300.66
19008817632001	01/04/2019	07/15/2021	\$1,300.66
19112897095001	04/19/2019	07/15/2021	\$1,430.72
19210873889001	07/08/2019	07/15/2021	\$1,430.72
19296845388001	10/21/2019	07/15/2021	\$1,430.72

20031822855001	01/28/2020	07/15/2021	\$1,430.72
20139845927001	05/15/2020	07/15/2021	\$1,459.92
20230855617001	08/12/2020	07/15/2021	\$1,459.92
20330841967001	11/23/2020	07/15/2021	\$1,459.92
21076836253001	03/10/2021	07/15/2021	\$1,459.92
21204829122001	07/20/2021	08/03/2021	\$1,459.92
21288839976002	10/13/2021	12/27/2021	\$1,459.92

77. Admitted.

78. This paragraph consists of Plaintiff's characterizations and legal conclusions regarding a Medicare regulation, to which no response is required. The Court is respectfully referred to the cited regulation.

1. October 30, 2021, Decision of ALJ Jason Earnhart

79. Admitted that Plaintiff sought review by an administrative law judge. The remainder of this paragraph consists of Plaintiff's characterization of that request, to which no response is required.

80. Admitted.

81. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*.

82. Admitted that the administrative law judge issued a decision on Plaintiff's claims. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of Plaintiff's characterization of that ALJ decision, to which no response is required.

1 83. Admitted that the administrative law judge issued a decision on Plaintiff's
2 claims. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
3 entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of
4 Plaintiff's characterization of that ALJ decision, to which no response is required.
5

6 84. Admitted that the administrative law judge issued a decision on Plaintiff's
7 claims. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
8 entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of
9 Plaintiff's characterization of that ALJ decision, to which no response is required.
10

11 85. Admitted that the administrative law judge issued a decision on Plaintiff's
12 claims. Defendant admits that he erroneously rejected Plaintiff's CGM claims after
13 entry of the Court's decision in *Olsen I*. The remainder of this paragraph consists of
14 Plaintiff's characterization of that ALJ decision, to which no response is required.
15
16

17 **2. November 2, 2021 Departmental Appeals Board Decision**

18 86. Admitted.

19 87. Admitted that Plaintiff sought review by the Departmental Appeals Board
20 (DAB). The remainder of this paragraph consists of Plaintiff's characterization of that
21 request, to which no response is required.
22

23 88. Admitted that the Departmental Appeals Board issued a decision on
24 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
25 characterization of that DAB decision, to which no response is required.
26

27 89. Admitted that the Departmental Appeals Board issued a decision on
28
ANSWER - 14

1 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
2 characterization of that DAB decision, to which no response is required.

3 90. Admitted that the Departmental Appeals Board issued a decision on
4 Plaintiff's request. The remainder of this paragraph consists of Plaintiff's
5 characterization of that DAB decision, to which no response is required.
6

7 VI. CAUSES OF ACTION

8 COUNT I

9
10 91. In this paragraph, Plaintiff repeats the paragraphs set forth above.
11 Defendant incorporates by reference his answers to all of the preceding paragraphs as
12 if fully set out herein.
13

14 92. This paragraph consists of a request for relief, to which no response is
15 required. To the extent that a response is deemed necessary, Defendant admits that he
16 erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen*
17 I. Defendant avers that he has since made appropriate payment to Plaintiff for the claims
18 that are the subject of this case. Defendant consents to administrative remand of this
19 matter for payment of any pending or future CGM claims from Plaintiff. Defendant
20 further affirmatively avers that on December 28, 2021, through notice-and-comment
21 rulemaking, the Centers for Medicare & Medicaid Services, U.S. Department of Health
22 and Human Services, issued a final rule entitled, *Medicare Program; Durable Medical*
23 *Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II*
24 *of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing*
25
26
27
28

1 *in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume*
2 *the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-*
3 *Contiguous Areas*, 86 Fed. Reg. 73,860, 73,860–73,911 (Dec. 28, 2021) (the “Final
4 Rule”). The Final Rule effectively replaces CMS 1682-R, which forms the basis of
5 Plaintiff’s claims in this case, is effective as of February 28, 2022. The recently issued
6 Final Rule makes clear that “claims submitted for CGM sensors and transmitters used
7 with insulin pumps are being denied inappropriately based on CMS–1682–R” because
8 that “Ruling only addressed the classification of CGM receivers as DME and did not
9 address coverage of CGM sensors and transmitters used with insulin pumps.” 86 Fed.
10 Reg. at 73,898. Further, the Final Rule states that the Secretary “now believe[s] that ...
11 glucose sensors and transmitters used with insulin pumps ... are primarily and
12 customarily used to serve a medical purpose.” *Id.* at 73,899.

13
14
15
16
17 93. This paragraph consists of a request for relief, to which no response is
18 required. To the extent that a response is deemed necessary, Defendant refers to its
19 answer in response to Paragraph 92. Defendant admits that he erroneously rejected
20 Plaintiff’s CGM claims after entry of the Court’s decision in *Olsen I*, avers that he has
21 since made appropriate payment to Plaintiff for the claims that are the subject of this
22 case, consents to administrative remand of this matter for payment of any pending or
23 future CGM claims from Plaintiff, and notes that the Final Rule effective February 28,
24 2022, resolves the classification as DME of future CGM claims from Plaintiff and other
25 similarly-situated CGM claimants.
26
27
28

COUNT II

94. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

95. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

96. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

//

COUNT III

97. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

98. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

99. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

//

COUNT IV

100. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

101. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

102. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

//

COUNT V

103. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

104. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

105. This paragraph consists of a request for relief, to which no response is required. To the extent that a response is deemed necessary, Defendant refers to its answer in response to Paragraph 92. Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as DME of future CGM claims from Plaintiff.

//

COUNT VI

106. In this paragraph, Plaintiff repeats the paragraphs set forth above. Defendant incorporates by reference his answers to all of the preceding paragraphs as if fully set out herein.

107. This paragraph consists of a legal conclusion to which no response is required.

108. This paragraph consists of a legal conclusion to which no response is required.

109. Denied.

110. This paragraph consists of a legal conclusion to which no response is required.

111. Denied.

112. Denied.

VII. PRAYER FOR RELIEF

The remaining paragraphs of the complaint contain Plaintiff's requested relief, to which no response is required. To the extent that a response is deemed necessary, Defendant admits that he erroneously rejected Plaintiff's CGM claims after entry of the Court's decision in *Olsen I*, avers that he has since made appropriate payment to Plaintiff for the claims that are the subject of this case, consents to administrative remand of this matter for payment of any pending or future CGM claims from Plaintiff, and notes that the Final Rule effective February 28, 2022, resolves the classification as

1 DME of future CGM claims from Plaintiff. Finally, Defendant admits Plaintiff is
2 entitled to costs and reasonable attorneys' fees in an amount to be determined by this
3 Court. With respect to any remaining requests for relief, Defendant denies that Plaintiff
4 is entitled to any other relief.
5

6 **AFFIRMATIVE DEFENSES**

7 1. To the extent Plaintiff is seeking an injunction requiring Defendant to grant
8 coverage for CGM claims, the Court lacks jurisdiction to grant such relief.
9

10 2. To the extent Plaintiff is seeking appointment of a special master to make
11 coverage decisions on CGM claims, the Court lacks jurisdiction to grant such relief.
12

13 RESPECTFULLY SUBMITTED: January 28, 2022.

14 Vanessa R. Waldref
15 United States Attorney

16 s/Brian M. Donovan
17 Brian M. Donovan
18 John T. Drake
19 Assistant United States Attorneys

20 Attorneys for Defendant
21
22
23
24
25
26
27
28

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Roger M. Townsend: rtownsend@bjtlegal.com

James Pistorino james@parrishlaw.com

And to the following non CM/ECF participants: N/A

s/ Brian M. Donovan
Assistant United States Attorney